CABINET FOR HEALTH AND FAMILY SERVICES

Department for Medicaid Services

Division of Administration and Financial Management

(Amendment)

907 KAR 1:019. Outpatient Pharmacy Program.

RELATES TO: KRS Chapter 13B, 205.510, 205.560, 205.561, 205.5631-205.5639, 205.564, 205.6316, 205.8451, 217.015, 217.822, 42 C.F.R. 430.10, 431.54, 440.120, 447.331, 447.332, 447.333, 447.334, 42 U.S.C. 1396a, 1396b, 1396c, 1396d, 1396r-8

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.561, 205.5632, 205.5634, 205.5639(2), 205.564(10), (13),

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has the responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed or opportunity presented by federal law for the provision of medical assistance to Kentucky's indigent citizenry. KRS 205.560 provides that the scope of medical care for which Medicaid shall pay is determined by administrative regulations promulgated by the cabinet. This administrative regulation establishes the provisions for coverage of drugs through the Medicaid Outpatient Pharmacy Program including the establishment of prior authorization procedures as authorized by KRS 205.5632 and Pharmacy and Therapeutics Advisory Committee provisions as authorized by KRS 205.564.

Section 1. Definitions. (1) "Brand name drug" means the registered trade name of a drug which was originally marketed under an original new drug application approved by the Food and Drug Administration.

(2) "Commissioner" is defined by KRS 205.5631(1).

(3) "Covered drug" means a drug for which the Department for Medicaid Services provides reimbursement if medically necessary and if provided, but not otherwise excluded, in accordance with Sections 2 and 3 of this administrative regulation.

(4) "Department" means the Department for Medicaid Services or its designated agent.

(5) "Department's Internet web site" or "web site" means the Internet web site maintained by the Department for Medicaid Services and accessible at http://www.chfs.ky.gov/dms.

(6) "Dosage form" means the type of physical formulation used to deliver a drug to the intended site of action, including a tablet, an extended release tablet, a capsule, an elixir, a solution, a powder, a spray, a cream, an ointment, or any other distinct physical formulation recognized as a dosage form by the Food and Drug Administration.

(7) "Drug list " means the Department for Medicaid Services' list which:

(a) Specifies:

1. Drugs, drug categories, and related items not covered by the department; and

2. Covered drugs requiring prior authorization or having special prescribing or dispensing restrictions or excluded medical uses; and

(b) May include information about other drugs, drug categories, or related items and dispensing and prescribing information.

(8) "Drug Management Review Advisory Board" or "DMRAB" or "board" means the board established pursuant to KRS 205.5636.

(9) "Effective" or "effectiveness" means a finding that a pharmaceutical agent does or does not have a significant, clinically- meaningful therapeutic advantage in terms of safety, usefulness, or clinical outcome over the other pharmaceutical agents based on pertinent information from a variety of sources determined by the department to be relevant and reliable.

(10) "Food and Drug Administration" means the Food and Drug Administration of the United States Department of Health and Human Services.

(11) "Generic drug" or "generic form of a brand name drug" means a drug which contains identical amounts of the same active drug ingredients in the same dosage form and which meets official compendia or other applicable standards of strength, quality, purity, and identity in comparison with the brand name drug.

(12) "Legend drug" means a drug so defined by the Food and Drug Administration and required to bear the statement: "Caution: Federal law prohibits dispensing without prescription".

(13) "Manufacturer" is defined in 42 U.S.C. 1396r-8(k)(5).

(14) "Medically necessary" or "medical necessity" means that a covered benefit is determined to be needed in accordance with 907 KAR 3:130.

(15) "Official compendia" or "compendia" is defined in 42 U.S.C. 1396r-8(g)(1)(B)(i).

(16) "Over-the-counter drug" or "OTC drug" means a drug approved by the Food and Drug Administration to be sold without bearing the statement "Caution: Federal law prohibits dispensing without prescription".

(17) "Pharmacy and Therapeutics Advisory Committee" or "committee" or "P&T Committee" means the pharmacy advisory committee established by KRS 205.564.

(18) "Prescriber" means a health care professional who, within the scope of practice under Kentucky licensing laws, has the legal authority to write or order a prescription for the drug that is ordered.

(19) "Recipient" means an individual eligible for and participating in a medical assistance program in the Department for Medicaid Services.

(20) "Secretary" means the Secretary of the Cabinet for Health and Family Services.

(21) "Supplemental rebate" means a cash rebate that offsets a Kentucky Medicaid expenditure and that supplements the Centers for Medicare and Medicaid Services National Rebate Program.

Section 2. Covered Benefits and Drug List. (1) A drug covered through the Outpatient Pharmacy Program shall be:

(a) Medically necessary;

(b) Approved by the Food and Drug Administration; and

(c) Prescribed for an indication that has been approved by the Food and Drug Administration or for which there is documentation in official compendia or peer-reviewed medical literature supporting its medical use.

(2) The department shall have a drug list which:

(a) Lists:

1. Drugs, drug categories, and related items not covered by the department and, if applicable, excluded medical uses for covered drugs; and

2. Maintenance drugs covered by the department;

(b) Specifies those covered drugs requiring prior authorization or having special prescribing or dispensing restrictions;

(c) Specifies those covered drugs for which the maximum quantity limit on dispensing may be exceeded;

(d) Lists covered over-the-counter drugs;

(e) Specifies those legend drugs which are permissible restrictions under 42 U.S.C. 1396r-8(d), but for which the department makes reimbursement;

(f) Specifies covered vaccines;

(g) May include a preferred drug list of selected drugs which have a more favorable cost to the department and which prescribers are encouraged to prescribe, if medically appropriate;

(h) May be updated monthly or more frequently by the department; and

(i) Shall be posted on the department's Internet web site.

(3) The department may implement drug treatment protocols requiring the use of medically-appropriate drugs which are available without prior authorization before the use of drugs which require prior authorization. The department may approve a request from the prescriber or a pharmacist for exemption of a specific recipient from this requirement based on documentation that drugs available without prior authorization:

(a) Were used and were not an effective medical treatment or lost their effectiveness;

(b) Are reasonably expected to not be an effective medical treatment;

(c) Resulted in, or are reasonably expected to result in, a clinically-significant adverse reaction or drug interaction; or

(d) Are medically contraindicated.

Section 3. Exclusions and Limitations. (1) The following drugs shall be excluded from coverage:

(a) A drug which the Food and Drug Administration considers to be:

1. A less-than-effective drug; or

2. Identical, related, or similar to a less-than-effective drug;

(b) A drug or its medical use in one (1) of the following categories unless the drug or its medical use is designated as covered in the drug list:

1. A drug if used for anorexia, weight loss, or weight gain;

2. A drug if used to promote fertility;

3. A drug if used for cosmetic purposes or hair growth;

4. A drug if used for the symptomatic relief of cough and colds;

5. A drug if used to promote smoking cessation;

6. Vitamin or mineral products other than prenatal vitamins and fluoride preparations;

7. An over-the-counter drug provided to a Medicaid nursing facility service recipient. An over-the-counter drug provided to a Medicaid nursing facility service recipient shall be considered a routine service which is already included in a nursing facility's reimbursement and shall be excluded from coverage via the Medicaid Outpatient Pharmacy Program;

8. A barbiturate;

9. A benzodiazepine;

10. A drug which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee; or

11. A drug utilized for erectile dysfunction therapy;

(c) A drug for which the manufacturer has not entered into or complied with a rebate agreement in accordance with 42 U.S.C. 1396r-8(a), unless there has been a review and determination by the department that it is in the best interest of a recipient for the department to make payment for the drug and federal financial participation is available for the drug;

(d) Except in accordance with subsection (6) of this section, a drug dispensed as part of, or incident to and in the same setting as, an inpatient hospital service, an outpatient hospital service, or an ambulatory surgical center service;

(e) A drug for which the department requires prior authorization if prior authorization has not been approved; and

(f) A drug that has reached the manufacturer's termination date, indicating that the drug may no longer be dispensed by a pharmacy.

(2) If authorized by the prescriber, a prescription for a:

(a) Controlled substance in Schedule III-V may be refilled up to five (5) times within a six (6) month period from the date the prescription was written or ordered, at which time a new prescription shall be required; or

(b) Except as prohibited in subsection (4), of this section, noncontrolled substance may be refilled up to eleven (11) times within a twelve (12) month period from the date the prescription was written or ordered, at which time a new prescription shall be re-quired.

(3) For each initial filling or refill of a prescription, a pharmacist shall dispense the drug in the quantity prescribed not to exceed a thirty-two (32) day supply unless:

(a) The drug is designated in the department's drug list as a drug exempt from the thirty-two (32) day dispensing limit in which case the pharmacist may dispense the quantity prescribed not to exceed a three (3) month supply or 100 units, whichever is greater;

(b) A prior authorization request has been submitted on the Drug Prior Authorization Request Form (MAP-82001) and approved by the department because the recipient needs additional medication while traveling or for a valid medical reason, in which case the pharmacist may dispense the quantity prescribed not to exceed a three (3) month supply or 100 units, whichever is greater;

(c) The drug is prepackaged by the manufacturer and is intended to be dispensed as an intact unit and it is impractical for the pharmacist to dispense only a month’s supply because one (1) or more units of the prepackaged drug will provide more than a thirty-two (32) day supply; or

(d) The prescription fill is for an outpatient service recipient, excluding an individual who is receiving supports for community living services in accordance with 907 KAR 1:145.

(4) A prescription fill for a maintenance drug for an outpatient service recipient who has demonstrated stability on the given maintenance drug, excluding an individual receiving supports for community living services in accordance with 907 KAR 1:145, shall be dispensed in a ninety-two (92) day supply unless:

(a) The department determines that it is in the best interest of the recipient to dispense a smaller supply;

(b) The recipient is covered under the Medicare Part D benefit in which case the de-

partment shall not cover the prescription fill; [;] or

(c) The recipient is expected to be covered under the Medicare Part D benefit effective January 1, 2006, and the dispensing occurs within ninety-two (92) days of January 1, 2006, the amount dispensed (and the amount that the department shall cover) shall equal the number of days between the dispensing and January 1, 2006. For example, if the dispensing occurs seventy-three (73) days prior to January 1, 2006, a seventy-three (73) day supply. If the dispensing occurs seventy-two (72) days prior to January 1, 2006, a seventy-two (72) day supply shall be dispensed and the department shall cover a seventy-two (72) day supply.

(5) The department may require prior authorization for a compounded drug that requires preparation by mixing two (2) or more individual drugs; however, the department may exempt a compounded drug or compounded drug category from prior authorization if there has been a review and determination by the department that it is in the best interest of a recipient for the department to make payment for the compounded drug or compounded drug category.

(6) An identification number shall be made available by a prescriber and shall be recorded on the pharmacy claim in accordance with the following:

(a) The medical license number of a physician for the state in which the physician practices or, for a physician who does not have a Kentucky state medical license number on file and who is enrolled in an approved graduate medical education program, the medical license number of the supervising physician;

(b) The license number, including applicable alpha characters, of a dentist, optometrist, or podiatrist for the state in which the individual practices;

(c) The registration number, including applicable alpha characters, of an advanced registered nurse practitioner registered in Kentucky or the registration number or license number, including applicable alpha characters, of an out-of-state advanced registered nurse practitioner for the state in which the individual practices; or

(d) The certification number, including applicable alpha characters, of a physician assistant for the state in which the individual practices.

(7) If it is determined by the department to be in the best interest of a recipient, the department may designate a legend drug that may be provided through prior authorization to a recipient in an inpatient facility that does not bill patients, Medicaid, or other third-party payers for health care services.

(8) A recipient who has been restricted to a single pharmacy in accordance with 907 KAR 1:677 shall be required to obtain non emergency pharmacy services from the pharmacy to which the recipient has been restricted.

(9) The department shall cover no more than a total of four (4) prescriptions, of which no more than three (3) shall be brand name prescriptions, per recipient per month unless the department determines that it is in the best interest of the recipient to cover any additional prescriptions whether brand name or generic.

[~~(a) Cover up to. three (3) brand name prescriptions per recipient per month unless the department determines that it is in the best interest of the recipient to cover any additional brand name prescription; and~~

~~(b) Cover unlimited generic prescriptions per recipient per month in accordance with the requirements and limitations established in this administrative regulation.~~]

(10) A refill of a prescription shall not be covered unless at least eighty (80) percent

of the prescription time period has elapsed.

Section 4. Prior Authorization Process. (1) To request prior authorization for a drug, the applicable Drug Prior Authorization Request Form, PPI and H2 Blocker Request Form, or the Brand Name Drug Request Form shall be completed and sent by fax or, if necessary, via the web-based application located at the Web site of http://kentucky.fhsc.com/providers/documents by mail, express-delivery service, or messenger service to the department. If drug therapy needs to be started on an urgent basis to avoid jeopardizing the health of the recipient or to avoid causing substantial pain and suffering, the completed request form may be sent to the department's urgent fax number or submitted to the department via the web-based application located at the Web site of http://kentucky.fhsc.com/providers/documents. A request shall be submitted in accordance with the following:

(a) Drug Prior Authorization Request Form. This form shall be used by the prescriber or the pharmacist to request prior authorization for a drug other than a drug classified as a proton pump inhibitor or a H2 receptor blocker or for a brand name only request if the generic form of the drug is available. This form may also be used by the pharmacist to obtain prior authorization for special dispensing requests involving exceptions to the thirty-two (32) day maximum quantity limit including additional drugs needed for travel or other valid medical reasons.

(b) Brand Name Drug Request Form. Except as provided in paragraphs (c) and (d) of this subsection, this form shall be used by the prescriber to request prior authorization for a brand name only request if the generic form of the drug is available, unless the department has specifically exempted the drug from the requirement to use this form. The

prescriber shall:

1. Complete a Brand Name Drug Request Form;

2. Include on the Brand Name Drug Request Form the handwritten phrase "brand medically necessary" or "brand necessary" and the prescriber's signature for each specific drug requested; and

3. Indicate on the Brand Name Drug Request Form:

a. Whether the recipient has received treatment with available generic forms of the brand name drug and the length of therapy; and

b. Why the recipient's medical condition is unable to be adequately treated with the generic forms of the drug.

(c) A Brand Name Drug Request Form shall not be required if:

1. It has been determined by the department to be in the best interest of a recipient not to require completion of a Brand Name Drug Request Form; and

2. The prescriber certifies that the brand name is medically necessary in accordance with subsection (3) of this section.

(d) PPI and H2 Blocker Request Form. This form shall be used to request prior authorization for a drug classified as a proton pump inhibitor or a H2 receptor blocker. This form may also be used for a brand name only request if the generic form of the proton pump inhibitor or H2 receptor is available and the prescriber completes the applicable section of the form and:

1. Includes on the form the handwritten phrase "brand medically necessary" or "brand necessary" and the prescriber's signature for each specific drug requested;

2. Indicates whether the recipient has received treatment with available generic forms

of the brand name drug and the length of therapy; and

3. Indicates why the recipient's medical condition is unable to be adequately treated with the generic forms of the drug.

(2) If a recipient presents a prescription to a pharmacist for a drug which requires prior authorization, the pharmacist:

(a) Shall, unless the form is one (1) which has to be completed by the prescriber, submit a request for prior authorization in accordance with subsection (1) of this section;

(b) Shall notify the prescriber or the prescriber's authorized representative that the drug requires prior authorization and:

1. If the prescriber indicates that a drug list alternative available without prior authorization is acceptable and provides a new prescription, shall dispense the drug list alternative; or

2. If the prescriber indicates that drug list alternatives available without prior authorization have been tried and failed or are clinically inappropriate or if the prescriber is unwilling to consider drug list alternatives, shall:

a. Request that the prescriber obtain prior authorization from the department; or

b. Unless the form is one (1) which has to be completed by the prescriber, submit a prior authorization request in accordance with subsection (1) of this section; or

(c) Except as restricted by subparagraphs 3 and 4 of this paragraph, may provide the recipient with an emergency supply of the prescribed drug in an emergency situation in accordance with all of the following:

1. The emergency situation shall:

a. Occur outside normal business hours of the department's drug prior authorization

office, except for medications dispensed to a long term care recipient in which an emergency supply may be dispensed after 5 p.m. EST; and

b. Exist if, based on the clinical judgement of the dispensing pharmacist, it would reasonably be expected that, by a delay in providing the drug to the recipient, the health of the recipient would be placed in serious jeopardy or the recipient would experience substantial pain and suffering;

2. At the time of the dispensing of the emergency supply, the pharmacist shall in accordance with subsection (1) of this section:

a. Submit a prior authorization request to the department's urgent fax number or to the department via the web-based application located at the Web site of http://kentucky.fhsc.com/providers/documents.asp; or

b. If applicable, notify the prescriber as soon as possible that an emergency supply was dispensed and that the prescriber is required to obtain prior authorization for the requested drug from the department;

3. An emergency supply shall not be provided for an over-the-counter (OTC) drug;

4. An emergency supply shall not be provided for a drug excluded from coverage in accordance with Section 3(1) (a), (b) and (c) of this administrative regulation; and

5. The quantity of the emergency supply shall be:

a. The lesser of a seventy-two (72) hour supply of the drug or the amount prescribed; or

b. The amount prescribed if it is not feasible for the pharmacist to dispense just a seventy-two (72) hour supply because the drug is packaged in such a way that it is not intended to be further divided at the time of dispensing but rather dispensed as origi-

nally packaged.

(3) In addition to the requirements of subsection (1) of this section, the prescriber shall be required to certify a brand name only request by including for each brand name drug requested the prescriber's signature and the phrase "Brand Medically Necessary" or "Brand Necessary" handwritten directly on:

(a) The prescription;

(b) The nursing facility order sheet; or

(c) A separate sheet of paper which includes the name of the recipient and the brand name drug requested and is attached to the original prescription or nursing facility order sheet.

(4) The department's notification of a decision on a request for prior authorization shall be made in accordance with the following:

(a) If the department approves a prior authorization request, notification of the approval shall be provided by telephone, fax or via the web-based application located at the Web site of http://kentucky.fhsc.com/providers/documents.asp to the party requesting the prior authorization and, if known, to the pharmacist.

(b) If the department denies a prior authorization request:

1. The department shall provide a denial notice:

a. By mail to the recipient and in accordance with 907 KAR 1:563; and

b. By fax, telephone, or if necessary by mail to the party who requested the prior authorization.

(5) The department may grant approval of a prior authorization request for a drug for a specific recipient for a period of time not to exceed 365 days. Approval of a new prior

authorization request shall be required for continuation of therapy subsequent to the expiration of a time-limited prior authorization request.

(6) Prior authorization of drugs for a Medicaid long-term care recipient in a nursing facility shall be in accordance with the following:

(a) The department may specify in its drug list specific drugs or drug classes which shall:

1. Not be exempted from prior authorization; or

2. Be exempt from prior authorization for Medicaid recipients in nursing facilities.

(b) A brand name drug for which the department requires completion by the prescriber of a Brand Name Drug Request Form in accordance with this section shall not be exempted from prior authorization.

Section 5. Placement of Drugs on Prior Authorization. (1) Except as excluded by Section 3(1)(a) to (c) of this administrative regulation, upon initial coverage by the Kentucky Medicaid program, a drug that is newly approved for marketing by the Food and Drug Administration under a product licensing application, new drug application, or a supplement to a new drug application and that is a new chemical or molecular entity shall be subject to prior authorization in accordance with KRS 205.5632.

(2) Upon request by the department, a drug manufacturer shall provide the department with the drug package insert information.

(3) The drug review process to determine if a drug shall require prior authorization shall be in accordance with the following:

(a) The determination as to whether a drug is in an excludable category specified in Section 3(1) of this administrative regulation shall be made by the department.

1. If a drug which has been determined to require prior authorization becomes available on the market in a new strength, package size, or other form that does not meet the definition of a new drug the new strength, package size, or other form shall require prior authorization.

2. A brand name drug for which there is a generic form that contains identical amounts of the same active drug ingredients in the same dosage form and that meets compendial or other applicable standards of strength, quality, purity, and identity in comparison with the brand name drug shall require prior authorization in accordance with Section 4 of this administrative regulation, unless there has been a review and determination by the department that it is in the best interest of a recipient for the department to cover the drug without prior authorization.

(b) The committee shall make a recommendation to the department regarding prior authorization of a drug based on:

1. A review of clinically-significant adverse side effects, drug interactions and contraindications and an assessment of the likelihood of significant abuse of the drug; and

2. An assessment of the cost of the drug compared to other drugs used for the same therapeutic indication and whether the drug offers a substantial clinically-meaningful advantage in terms of safety, effectiveness, or clinical outcome over other available drugs used for the same therapeutic indication. Cost shall be based on the net cost of federal rebate and supplemental rebate dollars.

(c) Within thirty (30) days of the date the committee’s recommendation is posted on the department’s web site, the secretary, in consultation with the commissioner and the department's pharmacy director, shall review the recommendations of the committee

and make the final determination whether a drug requires prior authorization. If the recommendation of the committee is not accepted, the secretary shall present the basis for the final determination in accordance with Section 8(3) of this administrative regulation.

(4) The department may exclude from coverage or require prior authorization for a drug which is a permissible restriction in accordance with 42 U.S.C. 1396r-8(d).

Section 6. Drug Management Review Advisory Board Meeting Procedures and Appeals. (1) A person may address the DMRAB if:

(a) The presentation is directly related to an agenda item; and

(b) Written notice has been given to the chairperson at least twenty-four (24) hours prior to the meeting.

(2) The DMRAB may establish time limits for presentations.

(3) The proposed agenda shall be posted on the department's Internet web site at least five (5) days prior to the meeting.

(4) An appeal of a final decision by the commissioner by a manufacturer of a product shall be in accordance with KRS 205.5639(5). The appeal request shall:

(a) Be in writing;

(b) State the specific reasons the manufacturer believes the final decision to be incorrect;

(c) Provide any supporting documentation; and

(d) Be received by the department within thirty (30) days of the manufacturer's actual notice of the final decision.

Section 7. Pharmacy and Therapeutics Advisory Committee Meeting Procedures. (1) A P&T Committee meeting agenda shall be posted as required by KRS 205.564(6).

(2) A P&T committee meeting shall be conducted in accordance with KRS 205.564.

(3) A public presentation at a P&T Committee meeting shall comply with the following:

(a)1. The time limit for a verbal presentation shall not exceed five (5) minutes in aggregate per drug per manufacturer or five (5) minutes by an individual speaking on a particular position;

2. A request to make a verbal presentation shall be submitted in writing via fax or e-mail to the department with a copy to the chair of the P&T Committee no later than forty-eight (48) hours in advance of the P&T Committee meeting;

3. An individual may only present new information (package insert changes, new indication or peer-reviewed journal articles) on a product or information on a new product; and

4. A presentation shall be limited to an agenda item; or

(b) Nonverbal comments, documents, or electronic media material (limited to package insert changes, new indication, or peer reviewed journal articles) shall be:

1.a. E-mailed to the department in a Microsoft compatible format (for example, Word, Power Point, Excel or other standard file formats including Adobe Acrobat's pdf format); or

b. Mailed to the department with a total of eighteen (18) copies mailed so that the department may distribute copies to P&T Committee members as well as to any other involved parties; and

2. Received by the department no later than seven (7) days prior to the P&T Committee meeting.

(4) The department may prepare written recommendations or options for drug review for the committee and shall post them as required by KRS 205.564(6).

(5) A recommendation by the committee shall require a majority vote.

(6) Recommendations of the committee shall be posted as required by KRS 205.564(8).

(7) A drug manufacturer may request that its name be placed on the department's distribution list for agendas of committee meetings. Placement of a drug manufacturer's name on the distribution list shall be valid through December 31 of each year, at which time the drug manufacturer shall be required to again request placement on the distribution list. To request placement of the drug manufacturer's name on the distribution list, the drug manufacturer shall submit the request in writing to the department and shall provide the following information about the drug manufacturer:

(a) Manufacturer's name;

(b) Mailing address;

(c) Telephone number;

(d) Fax number;

(e) E-mail address; and

(f) Name of a contact person.

(8) A drug manufacturer may be requested to submit a supplemental rebate proposal to the department based on a medication to be discussed at a designated P&T meeting.

(9) A supplemental rebate proposal submitted to the department shall be provided to P&T members during a closed session.

Section 8. Review and Final Determination by the Secretary. (1) An interested party

who is adversely affected by a recommendation of the committee may submit a written exception to the secretary in accordance with the following:

(a) The written exception shall be received by the secretary within seven (7) calendar days of the date of the committee meeting at which the recommendation was made; and

(b) Only information that was not available to be presented at the time of the committee's meeting shall be included in the written exception.

(2) After the time for filing written exceptions has expired, the secretary shall consider the recommendation of the committee and all exceptions that were filed in a timely manner prior to making a final determination. The secretary shall issue a final determination, and public notice of the final determination shall be posted on the department's Internet web site for six (6) months after which a copy of the final determination may be requested from the department.

(3) The secretary shall make a final determination in accordance with KRS 205.564(9).

(4) A final determination by the secretary may be appealed in accordance with KRS Chapter 13B. A decision of the secretary to remand the recommendation to the committee shall not constitute a final decision for purposes of an appeal pursuant to KRS Chapter 13B. An appeal request shall:

(a) Be in writing;

(b) Be sent by mail, messenger, carrier service, or express-delivery service to the secretary in a manner that safeguards the information;

(c) State the specific reasons the final determination of the secretary is alleged to be

erroneous or not based on the facts and law available to the committee and the secretary at the time of the decision;

(d) Be received by the secretary within thirty (30) days of the date of the posting of the final determination on the department's Internet web site; and

(e) Be forwarded by the secretary to the Administrative Hearings Branch of the Cabinet for Health and Family Services for processing in accordance with the provisions of KRS Chapter 13B.

Section 9. Appeal Rights. A Medicaid recipient may appeal the department's denial, suspension, reduction, or termination of a covered drug or decision regarding the amount of a drug dispensed based upon an application of this administrative regulation in accordance with 907 KAR 1:563.

Section 10. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "MAP-82001 Drug Prior Authorization Request Form, October 18, 2004, edition"; and

(b) "MAP-82101 Brand Name Drug Request Form, October 18, 2004, edition"; and

(c) "MAP-012802 PPI and H2 Blocker Request Form, October 18, 2004, edition."

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

907 KAR 1:019

REVIEWED:

Date

Shannon Turner, J.D., Commissioner
Department for Medicaid Services

Date

Mike Burnside
Undersecretary for Administrative and Fiscal Affairs

APPROVED:

Date

James. W. Holsinger, Jr., M.D., Secretary
Cabinet for Health and Family Services

A public hearing on this administrative regulation shall, if requested, be held on December 21, 2006, at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by December 14, 2006, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business January 3, 2006. Please send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573.

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 1:019
Cabinet for Health and Family Services
Department for Medicaid Services
Agency Contact Person: Stuart Owen or Stephanie Brammer-Barnes (564-6204)

(1) Provide a brief summary of:
(a) What this administrative regulation does: This administrative regulation establishes the provisions for coverage of drugs through the Medicaid outpatient pharmacy program.
(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish the provisions for coverage of drugs through the Medicaid outpatient pharmacy program.
(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing the provisions for coverage of drugs through the Medicaid outpatient pharmacy program.
(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation currently assists and will continue to assist in the effective administration of the authorizing statutes by establishing the provisions for coverage of drugs through the Medicaid outpatient pharmacy program.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
(a) How the amendment will change this existing administrative regulation: The amendment to this administrative establishes that the Department for Medicaid Services (DMS) shall cover no more than four (4) prescriptions per recipient per month unless DMS determines that it is in the best interest of the recipient to cover any additional prescriptions and clarifies maintenance drug prescription fill policy.
(b) The necessity of the amendment to this administrative regulation: The amendment to this administrative regulation is necessary to control rising pharmacy reimbursement costs in the Medicaid program in order to maintain the financial viability of the Department for Medicaid Services.
(c) How the amendment conforms to the content of the authorizing statutes: The amendment to this administrative regulation conforms to the content of the authorizing statutes by establishing that shall cover no more than four (4) prescriptions per recipient per month unless DMS determines that it is in the best interest of the recipient to cover any additional prescriptions and by clarifying maintenance drug prescription fill policy.
(d) How the amendment will assist in the effective administration of the statutes: The amendment to this administrative regulation will assist in the effective

administration of the authorizing statutes by establishing that shall cover no more than four (4) prescriptions per recipient per month unless DMS determines that it is in the best interest of the recipient to cover any additional prescriptions and by clarifying maintenance drug prescription fill policy.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: All Medicaid outpatient pharmacy providers will be affected by this administrative regulation.

(4) Provide an assessment of how the above group or groups will be impacted by either the implementation of this administrative regulation, if new, or by the change if it is an amendment: Pharmaceutical providers and manufacturers and recipients shall be affected in that DMS shall cover no more than four (4) prescriptions per month unless DMS determines that it is in the best interest of a recipient to cover any additional prescriptions.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:
(a) Initially: DMS estimates that the amendment to this administrative regulation could reduce expenditures by approximately $111.8 million annually ($77.1 million federal funds; $34.7 million state funds).
(b) On a continuing basis: DMS estimates that the amendment to this administrative regulation could reduce expenditures by approximately $111.8 million annually ($77.1 million federal funds; $34.7 million state funds).

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Federal funds authorized under the Social Security Act, Title XIX, and matching funds of general fund appropriations and collections will be used to fund the implementation and enforcement of this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: Neither an increase in fees nor funding will be necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any fees.

(9) Tiering: Is tiering applied? (Explain why tiering was or was not used)

Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the

agency. The “equal protection” and “due process” clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.

FEDERAL MANDATE ANALYSIS COMPARISON

Reg. No. 907 KAR 1:019 Agency Contact: Stuart Owen or Stephanie Brammer-Barnes (502-564-6204)

1. Federal statute or regulation constituting the federal mandate.

   Pursuant to 42 USC 1396a et. seq., the Commonwealth of Kentucky has exercised the option to establish a Medicaid Program for indigent Kentuckians. Having elected to offer Medicaid coverage, the state must comply with federal requirements contained in 42 USC 1396 et. seq.

2. State compliance standards.

   This administrative regulation restricts drug prescriptions to four (4) per recipient per month in accordance with state and federal law while allowing additional prescriptions if the Department for Medicaid Services (DMS) determines any additional prescriptions are in the best interest of a recipient.

3. Minimum or uniform standards contained in the federal mandate.

   This administrative regulation restricts drug prescriptions to four (4) per recipient per month in accordance with state and federal law while allowing additional prescriptions if the Department for Medicaid Services (DMS) determines any additional prescriptions are in the best interest of a recipient.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

   This administrative regulation restricts drug prescriptions to four (4) per recipient per month in accordance with state and federal law while allowing additional prescriptions if the Department for Medicaid Services (DMS) determines any additional prescriptions are in the best interest of a recipient.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

   This administrative regulation restricts drug prescriptions to four (4) per recipient per month in accordance with state and federal law while allowing additional prescriptions if the Department for Medicaid Services (DMS) determines any additional prescriptions are in the best interest of a recipient. This action is taken to maintain the viability of the Medicaid program.